

Amendments to the Claims

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims

1-47. (cancelled)

48. (new) A subcutaneous implantable cardioverter-defibrillator for delivering electrical cardioversion-defibrillation energy to a heart of a patient from a subcutaneous position, the cardioverter-defibrillator comprising:

a subcutaneous electrically active canister, wherein the canister houses a source of electrical energy, a capacitor, and operational circuitry; and

a subcutaneous lead connected to the canister, the lead including a subcutaneous cardioversion-defibrillation electrode spaced from the canister such that electrical cardioversion-defibrillation energy is delivered between the subcutaneous electrically active canister and the subcutaneous cardioversion-defibrillation electrode.

49. (new) The subcutaneous implantable cardioverter-defibrillator of claim 48, wherein the subcutaneous lead further includes one or more sensing electrodes.

50. (new) The subcutaneous implantable cardioverter-defibrillator of claim 48, wherein the subcutaneous lead further includes a first sensing electrode, and a second sensing electrode electrically insulated from and spaced from the first sensing electrode.

51. (new) The subcutaneous implantable cardioverter-defibrillator of claim 50, wherein the subcutaneous lead includes a proximal end connected to the canister, and a distal end, and wherein the first sensing electrode is located on the lead adjacent the distal end, the second sensing electrode is located on the lead about 1 to about 10 cm proximal from the first sensing electrode, and the cardioversion-defibrillation electrode is located on the lead proximal to the second sensing electrode.

52. (new) The subcutaneous implantable cardioverter-defibrillator of claim 50, wherein the subcutaneous lead includes a proximal end connected to the canister, and a distal end, wherein the first sensing electrode is located adjacent the distal end, the cardioversion-defibrillation electrode is located proximal to the first sensing electrode, and the second sensing electrode is located proximal to the cardioversion-defibrillation electrode.

53. (new) The subcutaneous implantable cardioverter-defibrillator of claim 50, wherein the subcutaneous lead includes a proximal end connected to the canister, and a distal end, wherein the cardioversion-defibrillation electrode is located adjacent the distal end, the first sensing electrode is located proximally to the cardioversion-defibrillation electrode, and the second sensing electrode is located about 1 to about 10 cm proximal to the first sensing electrode.

54. (new) The subcutaneous implantable cardioverter-defibrillator of claim 48, wherein the canister further includes one or more sensing electrodes.

55. (new) The subcutaneous implantable cardioverter-defibrillator of claim 48, wherein the operational circuitry is adapted for detecting one or more arrhythmic heart condition.

56. The subcutaneous implantable cardioverter-defibrillator of claim 48, wherein the operational circuitry is adapted for detecting a tachycardia rhythm.

57. (new) The subcutaneous implantable cardioverter-defibrillator of claim 48, wherein the operational circuitry is adapted for detecting a bradycardia rhythm.

58. (new) The subcutaneous implantable cardioverter-defibrillator of claim 48, wherein the operational circuitry is programmable.

59. (new) The subcutaneous implantable cardioverter-defibrillator of claim 48, wherein the operational circuitry is programmable such that upon the detection of a certain predetermined arrhythmic heart condition, electrical cardioversion-defibrillation energy is delivered between the subcutaneous electrically active canister and the subcutaneous cardioversion-defibrillation electrode.

60. (new) The subcutaneous implantable cardioverter-defibrillator of claim 48, wherein the subcutaneous canister includes one or more sensing electrodes, and the subcutaneous lead includes one or more sensing electrodes, the cardioverter-defibrillator further including means for selecting two sensing electrodes that provide adequate QRS wave detection.

61. (new) The subcutaneous implantable cardioverter-defibrillator of claim 48, further comprising a second subcutaneous lead connected to the canister, the second lead including a second subcutaneous cardioversion-defibrillation electrode spaced from the canister that serves as the opposite electrode from the canister and has the same polarity as the original subcutaneous electrode such that electrical cardioversion-defibrillation energy is delivered between the subcutaneous electrically active canister and the second subcutaneous cardioversion-defibrillation electrode.

62. (new) The subcutaneous implantable cardioverter-defibrillator of claim 48, further comprising a second subcutaneous lead connected to the canister, the second lead including a second subcutaneous cardioversion-defibrillation electrode spaced from the canister that serves as the opposite electrode from the original subcutaneous electrode and has the same polarity as the canister such that electrical cardioversion-defibrillation energy is delivered between the original subcutaneous cardioversion-defibrillation electrode and the second subcutaneous cardioversion-defibrillation electrode.

63. (new) The subcutaneous implantable cardioverter-defibrillator of claim 48, further comprising an attachment member located at the distal end of the subcutaneous lead for attaching the subcutaneous lead to nearby tissue.

64. (new) A subcutaneous implantable cardioverter-defibrillator for delivering electrical cardioversion-defibrillation energy to a heart of a patient from a subcutaneous position, the cardioverter-defibrillator comprising:

a subcutaneous electrically active canister, wherein the canister houses a source of electrical energy, a capacitor, and operational circuitry; and

a subcutaneous electrode that serves as the opposite electrode from the canister, the subcutaneous electrode being disposed such that when the canister is disposed in a predetermined subcutaneous position within the thorax of the patient such that electrical cardioversion-defibrillation energy is transmitted between the subcutaneous electrode and the subcutaneous canister during discharge.

65. (new) The subcutaneous implantable cardioverter-defibrillator of claim 64, wherein the subcutaneous implantable cardioverter-defibrillator further includes a subcutaneous lead connected to the canister, the lead including the subcutaneous electrode, the lead having a length, with the subcutaneous electrode being disposed along the length of the lead, such that when the canister is disposed in a predetermined subcutaneous position within the thorax of the patient, the lead extends in a predetermined subcutaneous path around the thorax of the patient.

66. (new) The subcutaneous implantable cardioverter-defibrillator of claim 65, wherein the subcutaneous lead further includes one or more sensing electrodes.

67. (new) The subcutaneous implantable cardioverter-defibrillator of claim 65, wherein the subcutaneous lead further includes a first sensing electrode and a second sensing electrode insulated and spaced from the first sensing electrode.

68. (new) The subcutaneous implantable cardioverter-defibrillator of claim 67, wherein the subcutaneous lead includes a proximal end connected to the canister, and a distal end, and wherein the first sensing electrode is located on the lead adjacent the distal end, the second sensing electrode is located on the lead about 1 to about 10 cm proximal from the first sensing

electrode, and the cardioversion-defibrillation electrode is located on the lead proximal to the second sensing electrode.

69. (new) The subcutaneous implantable cardioverter-defibrillator of claim 67, wherein the subcutaneous lead includes a proximal end connected to the canister, and a distal end, wherein the first sensing electrode is located adjacent the distal end, the cardioversion-defibrillation electrode is located proximal to the first sensing electrode, and the second sensing electrode is located proximal to the cardioversion-defibrillation electrode.

70. (new) The subcutaneous implantable cardioverter-defibrillator of claim 67, wherein the subcutaneous lead includes a proximal end connected to the canister, and a distal end, wherein the cardioversion-defibrillation electrode is located adjacent the distal end, the first sensing electrode is located proximally to the cardioversion-defibrillation electrode, and the second sensing electrode is located about 1 to about 10 cm proximal to the first sensing electrode.

71. (new) The subcutaneous implantable cardioverter-defibrillator of claim 64, wherein the canister further includes one or more sensing electrodes.

72. (new) The subcutaneous implantable cardioverter-defibrillator of claim 64, wherein the operational circuitry is adapted for detecting one or more arrhythmic heart conditions.

73. (new) The subcutaneous implantable cardioverter-defibrillator of claim 64, wherein the operational circuitry is adapted for detecting a tachycardia rhythm.

74. (new) The subcutaneous implantable cardioverter-defibrillator of claim 64, wherein the operational circuitry is adapted for detecting a bradycardia rhythm.

75. (new) The subcutaneous implantable cardioverter-defibrillator of claim 64, wherein the operational circuitry is programmable such that upon the detection of a certain predetermined

arrhythmic heart condition, electrical cardioversion-defibrillation energy is delivered between the subcutaneous electrically active canister and the subcutaneous cardioversion-defibrillation electrode.

76. (new) The subcutaneous implantable cardioverter-defibrillator of claim 65, wherein the subcutaneous canister includes one or more sensing electrodes, and the subcutaneous lead includes one or more sensing electrodes, the cardioverter-defibrillator further including means for selecting two sensing electrodes that provide adequate QRS wave detection.

77. (new) The subcutaneous implantable cardioverter-defibrillator of claim 65, further comprising a second subcutaneous lead connected to the canister, the second lead including a second subcutaneous cardioversion-defibrillation electrode spaced from the canister that serves as the opposite electrode from the canister and has the same polarity as the original subcutaneous electrode such that electrical cardioversion-defibrillation energy is delivered between the subcutaneous electrically active canister and the second subcutaneous cardioversion-defibrillation electrode.

78. (new) The subcutaneous implantable cardioverter-defibrillator of claim 65, further comprising a second subcutaneous lead connected to the canister, the second lead including a second subcutaneous cardioversion-defibrillation electrode spaced from the canister that serves as the opposite electrode from the original subcutaneous electrode and has the same polarity as the canister such that electrical cardioversion-defibrillation energy is delivered between the original subcutaneous cardioversion-defibrillation electrode and the second subcutaneous cardioversion-defibrillation electrode.

79. (new) The subcutaneous implantable cardioverter-defibrillator of claim 65, further comprising an attachment member located at the distal end of the subcutaneous lead for attaching the subcutaneous lead to nearby tissue.

80. (new) A method of implanting a subcutaneous cardioverter-defibrillator in a patient, the method comprising:

providing a subcutaneously implantable cardioverter-defibrillator including an electrically active canister that serves as either an anode or a cathode of the cardioverter-defibrillator, wherein the canister houses a source of electrical energy, a capacitor, and operational circuitry, and the cardioverter-defibrillator further includes a subcutaneous lead connected to the canister, the lead including a subcutaneous cardioversion-defibrillation electrode that serves as the opposite electrode from the canister such that electrical cardioversion-defibrillation energy is delivered between the subcutaneous electrically active canister and the subcutaneous cardioversion-defibrillation electrode;

inserting the subcutaneous canister in a predetermined subcutaneous position within the thorax of the patient;

inserting the subcutaneous lead in a predetermined subcutaneous path extending around a portion of the thorax of the patient so that the cardioversion-defibrillation electrode is positioned such that electrical cardioversion-defibrillation energy is delivered to the heart of the patient when electrical cardioversion-defibrillation energy is delivered between the subcutaneous electrically active canister and the subcutaneous cardioversion-defibrillation electrode.

81. (new) The method of claim 80, wherein inserting the subcutaneous lead includes using a curved introducer to make the subcutaneous path, and inserting the lead into the subcutaneous path.

82. (new) The method of claim 80, wherein inserting the subcutaneous canister and inserting the subcutaneous lead includes:

making a skin incision in the thoracic region of the patient;

inserting a curved introducer through the skin incision to make a subcutaneous path in the thoracic region such that a portion of the path is disposed at a location that if a straight line were drawn from the skin incision to the path termination the line would intersect the heart of the patient;

inserting the lead into the subcutaneous path such that the cardioversion-defibrillation electrode is disposed within the portion of the path;

placing the canister subcutaneously at the skin incision point; and
closing the skin incision.

83. (new) A method of providing anti-arrhythmia therapy to a patient having a heart, the method comprising:

providing a subcutaneous implantable cardioverter-defibrillator including a subcutaneous electrically active canister that serves as either an anode or a cathode of the cardioverter-defibrillator, wherein the canister houses a source of electrical energy, a capacitor, and operational circuitry, the cardioverter-defibrillator further including a subcutaneous lead connected to the canister, the lead including a subcutaneous cardioversion-defibrillation electrode spaced from the canister that serves as the opposite electrode from the canister;

inserting the subcutaneous canister in a predetermined subcutaneous position within the thorax of the patient;

inserting the subcutaneous lead in a predetermined subcutaneous path extending around a portion of the thorax of the patient such that the cardioversion-defibrillation electrode is positioned at a subcutaneous location spaced from the canister; and

delivering electrical cardioversion-defibrillation energy to the heart of the patient between the subcutaneous electrically active canister and the subcutaneous cardioversion-defibrillation electrode.

84. (new) The method of claim 83, wherein inserting the subcutaneous lead includes using a curved introducer to make the subcutaneous path, and inserting the lead into the subcutaneous path.

85. (new) The method of claim 83, wherein inserting the subcutaneous canister and inserting the subcutaneous lead includes:

making a skin incision in the thoracic region of the patient;

inserting a curved introducer through the skin incision to make a subcutaneous path in the thoracic region such that the a portion of the path is disposed at a location that if a straight line were drawn from the skin incision to the path termination the line would intersect the heart of the patient;

inserting the lead into the subcutaneous path such that the cardioversion-defibrillation electrode is disposed within the portion of the path;

placing the canister subcutaneously at the skin incision point; and
closing the skin incision.